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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 09/446,783 | 05/16/2000 | NEIL P. DESAI | 420052000126 | 2878 |
| 25226 | 7590 | 10/02/2007 | | |
| MORRISON & FOERSTER LLP | | | EXAMINER | |
| 755 PAGE MILL RD | | | VU, JAKE MINH | |
| PALO ALTO, CA 94304-1018 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/446,783 | DESAI ET AL. |
| | Examiner | Art Unit |
| | Jake M. Vu | 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 July 2007.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 73 and 74 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 73 and 74 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 07/03/2007.

- Claim 73 has been amended.
- Claims 73 and 74 are pending in the instant application.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 73 recites the newly amended limitation of "intermolecular"; however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrase. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant

disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant identified written support at line 22 of page 30 to line 2 of page 31, from line 26 of page 34 to line 11 of page 35, and in lines 21-23 of page 46 in the specification. However, the specification failed to disclose the "intermolecular" term. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient new written support in the original specification for the "limitations" indicated above.

Double Patenting

Claims 73 and 74 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,537,579; 5,362,478; 5,498421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686 **are maintained** for reasons of record in the previous office action filed on 01/03/2007.

Note, it is acknowledged that Applicant will address these rejections when the pending claims are found allowable.

Claim Rejections - 35 USC § 102

Claim 73 is rejected under 35 U.S.C. 102(e) as being anticipated by VIOLANTE et al (US 5,741,522) in light of MARKUS et al. *The disulfide bonds of human serum*

albumin and bovine gamma-globulin. J Am Chem Soc. 1957 Jan 05; 79(1): 134-39 **are withdrawn** in view of Applicant's amendment.

Claims 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by LIVERSIDGE et al (US 5,399,363) in light of MARKUS et al (cited supra) **are maintained** for reasons of record in the previous office action filed on 01/03/2007.

Response to Arguments

Applicant argues that LIVERSIDGE disclosed that the surface modifiers are essentially free of intermolecular crosslinkages, which is different from the invention as claimed by Applicant. The Examiner finds this argument unpersuasive, because LIVERSIDGE's "intermolecular crosslinkages" definition is different from Applicant's. Applicant's specification reveals that high shear from sonication or high-pressure homogenizer creates new crosslinking disulfide bonds from preexisting disulfide bonds on albumin (see Specification at pg. 30, line 23 to pg. 31, line 2). The Examiner assumes this new crosslinking disulfide bond is Applicant's definition of "intermolecular crosslinkages". LIVERSIDGE uses high shear from high shear media mill (see col. 6, line 38-39) and sonication (see col. 6, line 57) similar to Applicant's method to create this new crosslinking. Thus, the Examiner reasonably assumes LIVERSIDGE must have "intermolecular crosslinkages" by Applicant's implicit definition, since Applicant fails to explicitly define "intermolecular crosslinkages" in the specification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD
Art Unit 1618



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER